

K080194

510(k) SUMMARY

VIDAS® CEA (S) Assay

OCT 09 2008

A. Submitter Information

Submitter's Name: bioMérieux, Inc.
Address: 595 Anglum Road
Hazelwood, MO 63042

Contact Person: Sandra Perreand
Phone Number: 314-731-8594
Fax Number: 314-731-8689
Date of Preparation: September 29, 2008

B. Device Name

Trade Name: VIDAS® CEA (S) Assay

Common Name: Carcinoembryonic Antigen

Classification Name: System, Test, Carcinoembryonic Antigen

C. Predicate Device Name

Trade Name: Tosoh Medical, Inc. ST AIA Pack CEA Enzyme Immunoassay

D. Device Description

The assay principle combines a two-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. It is coated with anti-CEA monoclonal immunoglobulins (mouse). The other assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs).

After dilution, the sample is transferred into the well containing CEA antibody (conjugate) labeled with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR and to the conjugate to form a sandwich. Unbound compounds are eliminated during the first washing step.

A second incubation step is then performed with alkaline phosphatase-labeled anti-CEA polyclonal antibodies (goat). The unbound conjugate is then eliminated during washing steps.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

E. Intended Use

The VIDAS CEA (S) assay is VIDAS® CEA (S) is an automated quantitative test for use on the VIDAS instruments, for the quantitative measurement of Carcinoembryonic antigen (CEA) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CEA (S) assay is indicated as an aid in the monitoring of cancer patients in whom changing concentrations of CEA are observed.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the VIDAS CEA (S) assay to the predicate device is presented in the table below.

Item	VIDAS® CEA (S) Assay	TOSOH ST AIA-PACK CEA (K023893)
General Comparison		
Intended Use	VIDAS® CEA (S) is an automated quantitative test for use on the VIDAS instruments, for the quantitative measurement of Carcinoembryonic antigen (CEA) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CEA (S) assay is indicated as an aid in the monitoring of cancer patients in whom changing concentrations of CEA are observed.	ST AIA-PACK CEA is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of Carcinoembryonic Antigen (CEA) in human serum to aid in the management of cancer patients in whom changing concentrations of CEA are observed on TOSOH AIA System analyzers.
Specimen	Serum	Serum
Analyte	Carcinoembryonic Antigen	Carcinoembryonic Antigen
Antibody	Goat polyclonal CEA antibody; mouse monoclonal CEA antibody	Two mouse monoclonal CEA antibodies
Assay Principle	Two antibody "sandwich" binding of CEA. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound	Two antibody "sandwich" binding of CEA. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound
Automated	Yes	Yes
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Two-site immunoenzymometric assay
Sample Volume	200 µL	100 µL
Traceability/Standardization	Master curve for each kit lot and each calibrator lot are traceable to reference standards established by bioMérieux, Inc. and the CarcinoEmbryonic Antigen 1st International Reference Preparation provided by the National Institute of Biological Standards and Controls (NIBSC) code 73/601 (1975)	Each calibrator lot are traceable to WHO 1 st International Reference Preparation (IRP) 73/601 (1975)
Measurement range	0.5 – 200 ng/mL	0.5 – 100 ng/mL

G. Performance Data

A summary of the non-clinical and clinical test results is presented in the table below.

Test	VIDAS® CEA (S) Assay	TOSOH ST AIA-PACK CEA (K023894)
Non-clinical (Analytical) Comparison		
Intra-Assay Precision	<p>n = 40 runs (across sites and lots)</p> <p>Pool C: Mean = 3.4 ng/mL CV range = 2.7 – 4.4%</p> <p>Pool B: Mean = 25 ng/mL CV range = 3.5 – 4.4%</p> <p>Pool A: Mean = 160 ng/mL CV range = 3.7 – 5.3%</p>	<p>n = 20 replicates</p> <p>Sample 1: Mean = 4.56 ng/mL CV = 4.3%</p> <p>Sample 2: Mean = 19.74 ng/mL CV = 3.6%</p> <p>Sample 3: Mean = 45.64 ng/mL CV = 4.0%</p> <p>Sample 4: Mean = 79.11 ng/mL CV = 3.1%</p>
Inter-Run Precision	<p>n = 40 runs (across sites and lots)</p> <p>Pool C: Mean = 3.4 ng/mL CV range = 0 – 1.3%</p> <p>Pool B: Mean = 25 ng/mL CV range = 0 – 1.6%</p> <p>Pool A: Mean = 160 ng/mL CV range = 0 – 1.0%</p>	<p>n = 20 runs</p> <p>Sample 1: Mean = 5.26 ng/mL CV = 3.9%</p> <p>Sample 2: Mean = 22.81 ng/mL CV = 3.3%</p> <p>Sample 3: Mean = 50.17 ng/mL CV = 3.6%</p> <p>Sample 4: Mean = 91.52 ng/mL CV = 3.2%</p>
Limits of Detection	< 0.5 ng/mL	0.5 ng/mL

Clinical Comparison		
Item	VIDAS® CEA (S) Assay	TOSOH ST AIA-PACK CEA (K023893)
Reference Range	Non-smoker: Female ≤ 2.44 ng/mL Male ≤ 3.23 ng/mL Smoker: Female ≤ 3.53 ng/mL Male ≤ 6.44 ng/mL	Non-smoker: ≤ 3.07 ng/mL Smoker: ≤ 6.17 ng/mL
Method Comparison		
Methods	X = TOSOH ST AIA-Pack CEA; y = VIDAS® CEA (S)	
Number of patients	1,307 samples	
Results	Slope = 0.9410 (95% confidence interval = 0.8238 to 1.0582) Intercept = -1.2905 (95% confidence interval = -1.6812 to -0.8998)	

H. Conclusion

The VIDAS® CEA (S) Assay is substantially equivalent to the Tosoh Medical, Inc. ST AIA Pack CEA Assay.

The 510(k) summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 09 2008

bioMérieux, Inc.
c/o Ms. Sandra Perreand
Senior Director, North American Regulatory Affairs
595 Anglum Road
Hazelwood, MO 63042

Re: k080194

Trade/Device Name: Vidas® CEA (S)

Regulation Number: 21 CFR 866.6010

Regulation Name: Tumor associated antigen immunological test systems

Regulatory Class: Class II

Product Code: DHX

Dated: September 29, 2008

Received: September 30, 2008

Dear Ms. Perreand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

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will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080194

Device Name: VIDAS® CEA (S)

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Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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